

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

GARY BRYAN BRACKIN,)	
individually and in his capacity as Surviving)	
Spouse of PAMELA W. BRACKIN,)	
Deceased,)	
)	Case No. 2:17-cv-2101
Plaintiff,)	
)	
v.)	
)	
MEDTRONIC, INC., et. al,)	
)	
Defendants.)	
_____)	

**DEFENDANTS MEDTRONIC, INC.’S AND MEDTRONIC MINIMED, INC.’S
MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF
WILLIAM J. VIGILANTE, JR., PH.D, CPE**

Defendants Medtronic, Inc. and Medtronic MiniMed, Inc. (collectively, the “Medtronic Defendants”), pursuant to Federal Rule of Evidence 702, 403 and 104 and *Daubert v. Merrell-Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1983), respectfully request that the Court limit or exclude from trial certain testimony by Plaintiff’s expert William J. Vigilante, Jr., Ph.D, CPE (“Dr. Vigilante”), and any opinions that may arise out of the same.

This is a products liability case in which Plaintiff Gary Brackin seeks damages related to the death of his wife, Pamela Brackin. Plaintiff has designated Dr. Vigilante as a human factors expert, to testify as an expert about (1) the adequacy of instructions and warnings for the device at issue; (2) the adequacy of the Medtronic Defendants’ human factors analysis in designing the device at issue; and (3) medical causation for Pamela Brackin’s injury and death. For the reasons set forth in the Medtronic Defendants’ contemporaneously filed Memorandum of Law in Support of Motion to Exclude Opinions and Testimony of Dr. Vigilante, Dr. Vigilante is not

qualified to provide expert opinions related to FDA-regulated medical devices or any aspect of medical causation. Moreover, the whole of his causation testimony should be excluded because it is based on unsubstantiated assumptions and he has not used a reliable methodology to arrive at his opinions. Accordingly, Dr. Vigilante's proposed testimony is inadmissible under the Federal Rules, and the Court should exclude his written report and proposed testimony.

In support of this Motion to Exclude, the Medtronic Defendants rely upon their Memorandum of Law in Support of their Motion and attached exhibits filed contemporaneously herewith. The Medtronic Defendants request oral argument on their Motion. Oral argument would be helpful to the Court to further address the *Daubert* analysis as applied to Dr. Vigilante's proposed testimony and opinions.

WHEREFORE, the Medtronic Defendants respectfully request that the Court enter an order:

1. GRANTING this Motion and PRECLUDING Dr. Vigilante from offering any testimony or opinions on labeling, warnings, or human factors analysis with respect to FDA regulated medical devices; and
2. PRECLUDING Dr. Vigilante from offering any engineering or design testimony or opinions about FDA regulated medical devices; and
3. PRECLUDING Dr. Vigilante from offering any testimony or opinions regarding medical causation for Ms. Brackin's injury and death;
4. PRECLUDING Dr. Vigilante from offering any testimony or opinions about causation for Ms. Brackin's injury and death; and
5. PRECLUDING Dr. Vigilante from propounding any new, supplemental or revised causation opinions with regard to Medtronic Defendants; and

6. ORDERING such other relief as the Court deems just and proper.

Respectfully submitted,

Dated: September 14, 2018

GREENBERG TRAURIG, LLP

/s/ Lori G. Cohen

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CERTIFICATE OF SERVICE

This is to certify that I have this day served a copy of the within and foregoing
**DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC MINIMED, INC.'S MOTION
TO EXCLUDE OPINIONS AND TESTIMONY OF WILLIAM J. VIGILANTE, JR.,
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This 14th day of September, 2018.

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